**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF UTAH**

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| LINDA P. SMITH,<br><br>Plaintiff,<br><br>v.<br><br>XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,<br><br>Defendant. | ) | Case No. 1:21-cv-47 (CMR) |

**Defendant's Response to Plaintiff's Motion for Status Conference**

As noted in plaintiff's motion, ECF No. 49 ("Pl.s' Mot."), defendant the Secretary of Health and Human Services does not oppose the request for a status conference or ruling on the pending motions for summary judgment. Defendant writes separately to provide the Court with more information with respect to a recent regulatory development relevant to the claims at issue in this case.

On December 28, 2021, through notice-and-comment rulemaking, the Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services, issued a final rule entitled, *Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas*, 86 Fed. Reg. 73,860, 73,860–73,911 (Dec. 28, 2021) (the "DME Final Rule").[1] Among other things, the final rule observes:

[1] The Secretary previously alerted the Court to the proposed rulemaking that led to the DME Final Rule. *See, e.g.*, ECF No. 32 at 3 (Def.'s Cross-Mot. for SJ & Opp. to Pl's Mots. For SJ); ECF No. 47 at 2, 12 (Def.'s SJ Reply); *id.* at 2 (discussing comments made by the Secretary's counsel at the initial hearing in this case).

> [Medicare] beneficiaries are currently using disposable continuous glucose sensors and transmitters that have not been approved or cleared by the FDA to replace a blood glucose monitor for use in making diabetes treatment decisions with insulin infusion pumps that also function as ''adjunctive'' or ''non-therapeutic'' [continuous glucose monitor ("CGM")] receivers. Beneficiaries are using the readings from these disposable sensors that are received and displayed by the insulin pump to help manage their diabetes. *Claims submitted for CGM sensors and transmitters used with insulin pumps are being denied inappropriately based on CMS–1682–R even though this Ruling only addressed the classification of CGM receivers as DME and did not address coverage of CGM sensors and transmitters used with insulin pumps.*

*Id.* at 73,898 (emphasis added).[2] The DME Final Rule further states:

> [W]e believe that *disposable continuous glucose sensors and transmitters that work in conjunction with an insulin pump that also operates as a continuous glucose monitor's receiver component* to alert the patient about potentially dangerous glucose levels while they sleep *are primarily and customarily used to serve a medical purpose*. We now believe that because adjunctive CGMs or *adjunctive continuous glucose sensors and transmitters used with insulin pumps* can provide information about potential changes in glucose levels while a beneficiary is sleeping and is not using a blood glucose monitor, *these* CGMs or *CGM functions on insulin pumps are primarily and customarily used to serve a medical purpose*.

*Id.* at 73,899 (emphasis added).

In light of the foregoing, the Secretary renews his request to enter judgment in favor of plaintiff and to remand to the Secretary to pay the claims at issue in this case. As the Court is aware, plaintiff Linda Smith seeks review of a decision of the Medicare Appeals Council, which denied three claims for coverage under Medicare Part B. One claim concerned a MiniMed 630G system with Smartguard—a durable insulin pump that also functions as a continuous glucose

[2] Additionally, the final rule supersedes CMS Ruling CMS–1682–R (Jan. 2017) with respect to CGM systems and classifies such systems as durable medical equipment ("DME"). 86 Fed. Reg. at 73,896–902. Plaintiff's motion asserts without citation that the Secretary intends to continue to rely on CMS Ruling CMS–1682–R to reject CGM claims for the next ~14 months. Pl.'s Mot. at 2. The regulations promulgated in the DME Final Rule take effect on February 28, 2022. 86 Fed. Reg. at 73,860. However, contrary to plaintiff's unsupported assertions, Pl.'s Mot. at 2, nothing prevents the Secretary from considering the reasoning in the DME Final Rule and applying it to claims with dates of service earlier than February 28, 2022.

monitor—while the others concerned disposable glucose sensors for use with that device. The MAC's denial of these claims was based at least in part on its reading of CMS Ruling CMS–1682–R. At the outset of this case, pursuant to Local Civil Rule 7-4(a)(2)(B), the Secretary of Health and Human Services confessed error as to all three claims. *See* ECF No. 10 at 1 (Def.'s Resp. to Compl.). At that time, the Secretary urged this Court to enter judgment in favor of Mrs. Smith and to remand for payment of the claim for the insulin pump, and "determination of whether the sensors should be covered as reasonable and necessary for the operation of the insulin pump." *Id.* at 2. Plaintiff opposed the remand on the ground that the "resolution proposed by the Secretary [would] not provide Mrs. Smith the relief she seeks" because the proposed resolution sought "a remand to the Secretary for … a determination of *whether* the sensors should be covered." ECF No. 17 (Pl.'s Resp. to June 24, 2021 Order) (emphasis added).

The recently issued DME Final Rule makes clear that "claims submitted for CGM sensors and transmitters *used with insulin pumps* are being denied inappropriately based on CMS–1682–R" because that "Ruling only addressed the classification of CGM receivers as DME and did not address coverage of CGM sensors and transmitters used with insulin pumps." 86 Fed. Reg. at 73,898 (emphasis added). Further, the DME Final Rule states that the Secretary "now believe[s] that … *glucose sensors and transmitters used with insulin pumps* … are primarily and customarily used to serve a medical purpose." *Id.* at 73,899. These sentences pertain to Ms. Smith's claims in this case because the system she uses is an insulin pump that also has CGM capability, and she seeks reimbursement for the system itself as well as for disposable sensors used with it. Therefore, in light of the Secretary's prior confession of error as to all three claims at issue in this case, and given the DME Final Rule and the Secretary's representation that he would pay the three claims, the Secretary respectfully requests that the Court enter judgment in favor of plaintiff on these grounds and remand to the Secretary for payment of the three claims at issue in this case.

Plaintiff's instant motion mentions a more recent administrative claim that is not discussed in the Complaint or part of the administrative record in this case, and thus, it is not

properly before the Court. Pl.'s Mot. at 1. While plaintiff's counsel only provided undersigned counsel a copy of the December 17, 2021, claim appeal denial letter sent by the Medicare Qualified Independent Contractor ("QIC"), and not the underlying claim documentation, it appears that the above-quoted portions of the DME Final Rule may also be relevant to Ms. Smith's claim in that matter. If so, she could appeal the decision on that basis to the Administrative Law Judge.

As to the three claims that *are* at issue in this case, the Court should enter judgment in favor of plaintiff as discussed above and remand those three claims to the Secretary for payment without holding a status conference. Should the Court reach the pending summary judgment cross-motions (ECF Nos. 28, 29, 31), the Court could decide them without a status conference or hearing. That said, defendant does not oppose plaintiff's request for a status conference, and stands ready to participate in such conference or a hearing if the Court would find it helpful.

Dated: January 7, 2021

Respectfully submitted,

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